UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

GARY W. KLEINMAN, Individually And On Behalf of All Others Similarly Situated,

Plaintiff,

V.

ELAN CORPORATION, PLC, PFIZER, INC., as successor-in-interest to WYETH, INC., G. KELLY MARTIN and LARS EKMAN,

DECEIVE DIL 23 2010 U.S.D.C. S.D. N.Y. CASHIERS

Civil Action No. 5630

CLASS ACTION

COMPLAINT FOR VIOLATIONS
OF THE FEDERAL SECURITIES LAWS

DEMAND FOR A JURY TRIAL

Defendants.

- 1. Plaintiff Gary W. Kleinman ("Plaintiff") brings this class action for violations of the federal securities laws on behalf of all purchasers of call options of Elan Corporation, plc ("Elan" or the "Company") between June 17, 2008 and July 29, 2008, inclusive ("Class Period"). Such purchasers, along with Plaintiff, are collectively referred to herein as the "Class." This Complaint is brought against Elan, the Company's President, Chief Executive Officer, and Director, G. Kelly Martin, the Company's Chairman of the Science and Technology Committee of the Board, Lars Ekman, and Pfizer, Inc. ("Pfizer"), as successor-in-interest to Wyeth, Inc. ("Wyeth") (collectively, "Defendants").
- 2. This Complaint is alleged upon personal knowledge as to Plaintiff's own acts, and upon information and belief as to all other matters, based upon Plaintiff's counsel's investigation, including review of Elan's and Wyeth's public filings with the United States Securities and Exchange Commission ("SEC"); webcasts; wire and press releases published by and regarding Elan and Wyeth; and information available in the media and on the Internet. Additional facts supporting the allegations contained herein are known only to the Defendants or are exclusively

within their control. Plaintiff believes that substantial additional evidentiary support exists for the allegations set forth in this Complaint that will be revealed after a reasonable opportunity for discovery.

INTRODUCTION AND OVERVIEW

- 3. Elan's American Depositary Receipts ("Elan ADRs") trade on the New York Stock Exchange. Elan's publicly traded call options ("call options") are derivative of, and trade in tandem with, Elan ADRs. The call options give the purchasers of those options the right to buy Elan ADRs at a set price.
- 4. Elan is a neuroscience-based biotechnology company. Elan's Biopharmaceuticals unit engages in research, development and commercial activities involving Alzheimer's disease, a progressive brain disorder and form of dementia that gradually destroys a person's memory and ability to learn, reason, make judgments, communicate, and carry out activities of daily living. Pharmaceutical Research and Manufacturers of America has stated that there are more drugs in the neurological disease pipeline for the treatment of Alzheimer's disease that affects more than five million people in the United States than for any other illness except pain.
- 5. In its effort to join this expanding market, Elan and Wyeth jointly developed bapineuzumab (AAB-001), an experimental humanized monoclonal antibody for the treatment of mild to moderate Alzheimer's disease. Bapineuzumab was designed to clear toxic beta amyloid from the brain, with the hope that this might slow or prevent the progressive neurodegeneration in the brain associated with Alzheimer's disease. In clinical trials, Elan and Wyeth dosed patients with bapineuzumab to bind and clear the beta-amyloid peptide plaques that appear to be the main constituent of amyloid plaques in the brain of Alzheimer's disease patients. A purported advantage of bapineuzumab is that the treatment reduces or eliminates safety problems associated with therapies that stimulate an immune response.

- 6. On June 17, 2008, Elan and Wyeth issued a press release regarding the phase 2 trial ("Phase 2 Trial") of Bapineuzumab: "Elan and Wyeth Announce Encouraging Top-line Results from Phase 2 Clinical Trial of Bapineuzumab for Alzheimer's Disease." The press release boasted of "statistically significant and clinically meaningful benefits in the patients in the study who did not carry the gene [Apolipoprotein E4 ("ApoE4")] that increases the risk of having Alzheimer's disease." While the press release stated that the study "did not attain statistical significance on the primary efficacy endpoints in the overall study population," it failed to disclose the magnitude of the miss, the absence of dose response, the unusually swift decline of the placebo patients, or the troubling safety results, including three deaths reported in the group taking bapineuzumab compared to none in the placebo group, development of a potentially dangerous accumulation of fluid in the brain known as vasogenic edema in nearly 10% of the patients taking bapineuzumab, and nine additional adverse effects that occurred two or more times as often in patients taking bapineuzumab.
- 7. As a result of the June 17, 2008 announcement, the price of Elan ADRs rose from \$27.11 to \$30 in one day, or 10.7%, on extremely high trading volume. The price of Elan ADRs continued to rise during the Class Period, closing at \$36.82 on July 10, 2008.
- 8. On July 29, 2008, Elan and Wyeth issued a press release, presented at Alzheimer's Association's International Conference on Alzheimer's Disease in Chicago, Illinois ("ICAD Conference"), a major medical meeting of the Alzheimer's Association, and hosted a webcast. As a result of the press release, the ICAD Conference and the webcast, investors learned for the first time the true facts concerning the Phase 2 Trial of AAB-001. The detailed findings revealed that only the patients lacking the ApoE4 mutation, about a third of all Alzheimer's patients, showed a slower decline in brain functions with the bapineuzumab treatment.
 - 9. Further, the Phase 2 Trial showed that some patients' results were worse than with

the placebo in respect to some measures of cognition and function. Also materially, efficacy did not increase with the dose.

- 10. Additionally, the Phase 2 Trial only showed a 5 point effect on the standard survey scale (ADAS-Cog), compared with existing Alzheimer's drugs that usually show around a 3 point effect. The drug also showed little or no benefit and more side effects in the other two-thirds of the patients who have the ApoE4 mutations. Therefore, improvement over placebo did not reach significance and could have been random in the overall trial of all patients.
- 11. As a result of these disclosures on July 29, 2008, the price of Elan ADRs plunged from \$33.75 to \$19.63 in one day, a 42% decline, as artificial inflation came out of the price, on a volume of 82,162,900 shares.
- 12. During the Class Period, Defendants materially misled the investing public, thereby inflating Elan ADRs by publicly issuing false and misleading statements and failing to disclose the full, unfavorable results of the Phase 2 Trial of bapineuzumab. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of Elan ADRs, members of the Class (purchasers of call options), including Plaintiff, have suffered significant losses and damages.
- 13. When these facts were finally disclosed, the price of Elan ADRs plunged 42% in one day as the artificial inflation caused by Defendants' false and misleading statements came out of the price. The adverse results of the Phase 2 Trial were a material setback for the development of bapineuzumab. They meant that the phase 3 trials ("Phase 3 Trials") would likely have to run their full 18-month courses before any U.S. Food & Drug Administration ("FDA") approval was possible. Indeed, the disappointing results of the Phase 2 Trial virtually eliminated any chance that Elan and Wyeth could receive FDA approval before the Phase 3 Trials were finished. Even if bapineuzumab is eventually approved by the FDA, this delay pushes any revenues further into the

future and reduces their then-present value. Finally, the previously undisclosed and negative Phase 2 Trial data reduced the likelihood that bapineuzumab was greatly superior to Alzheimer's drugs already on the market, limiting its commercial potential.

JURISDICTION AND VENUE

- 14. The claims asserted arise under §§10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act"), 15 U.S.C. §§78j(b) and 78t(a), and Rule 10b-5, 17 C.F.R. §240.10b-5, promulgated thereunder. Jurisdiction is conferred by §27 of the Exchange Act, 15 U.S.C. §78aa.
- During the Class Period, the bulk of the Company's employees, including its Chief Executive Officer ("CEO"), research department, communications department, and general counsel were all in the United States. Elan submitted SEC filings on Form 20-F during the Class Period. The Phase 2 Trial at issue was conducted at 26 domestic sites in 18 different states, including New York. During the Class Period, Defendants issued the June 17, 2008 press release from Dublin, Ireland and Madison, New Jersey, the July 29, 2008 press release from Chicago, Illinois, and the July 29, 2008 statements at the ICAD Conference in Chicago, Illinois.
- 16. The vast majority of the harm caused by Defendants' fraud also occurred in the United States, as over 85% of Elan's equities traded on the New York Stock Exchange ("NYSE"). Additionally, all of Elan's publicly traded options on its NYSE ADRs trade in the United States.
- 17. Venue is proper here pursuant to §27 of the Exchange Act. Elan conducts business in this District and Elan ADRs trade on the NYSE, which is located in this District. During the Class Period, Elan's CEO, defendant G. Kelly Martin, was based in this District. Also, the Phase 2 Trial at issue was conducted, in part, in this District.

THE PARTIES

18. Plaintiff Gary W. Kleinman ("Plaintiff") purchased Elan's call options during the

Class Period and suffered economic loss and damages when the truth about Elan that was misrepresented and omitted during the Class Period was revealed. The Plaintiff's Certification of Gary W. Kleinman containing a detailed list of his transactions in Elan during the Class Period is attached hereto as Exhibit A.

- 19. During the Class Period, defendant Elan maintained operations at 875 Third Avenue, 3rd Floor, New York, New York and the Elan ADRs traded on the NYSE, an efficient market. During the Class Period, Elan's CEO was based in New York, New York, the Company's research and communication functions were based in San Francisco, California, and its general counsel was in Pennsylvania. The bulk of the Company's employees, including nearly all of its researchers, were and continue to be in the United States.
- 20. Defendant Wyeth was a Delaware corporation and, prior to its acquisition by Pfizer in October 2009, maintained its headquarters in Madison, New Jersey. Wyeth engaged in the discovery, development, manufacture, distribution and sale of a diversified line of products in three primary businesses: Wyeth Pharmaceuticals, Wyeth Consumer Healthcare, and Fort Dodge Animal Health. Pharmaceuticals included branded human ethical pharmaceuticals, biotechnology products, vaccines and nutritional products. Pharmaceuticals products included neuroscience therapies, musculoskeletal therapies, vaccines, nutritional products, anti-infectives, women's health care products, hemophilia treatments, gastroenterology drugs, immunological products and oncology therapies. Wyeth is now a wholly-owned operating subsidiary of Pfizer.
- 21. Defendant Pfizer, Inc. is the world's largest pharmaceutical company, ranking number one in sales in the world and generating over \$46 billion in revenues. Pfizer is a Delaware corporation, headquartered in New York, New York, with its research headquarters in Groton, Connecticut. On January 26, 2009, Pfizer agreed to buy Wyeth for \$68 billion. The deal was completed on October 15, 2009.

- 22. Defendant G. Kelly Martin ("Martin") was Elan's President and CEO at all relevant times. Defendant Martin was formerly president of the International Private Client Group and a member of the executive management and operating committee of Merrill Lynch & Co., Inc. He spent over 20 years at Merrill Lynch in a broad array of operating and executive responsibilities on a global basis.
- 23. Defendant Lars Ekman ("Ekman") was a member of the Board of Directors and Chairman of the Science and Technology Committee of the Board throughout the Class Period. Prior to joining Elan, defendant Ekman was executive vice president, R&D, at Schwarz Pharma AG since 1997. From 1984 to 1997, defendant Ekman was employed in a variety of senior scientific and clinical functions at Pharmacia (now Pfizer). Defendant Ekman is a board certified surgeon with a Ph.D in experimental biology and has held several clinical and academic positions in both the United States and Europe. Defendant Ekman obtained his Ph.D and MD from the University of Gothenburg, Sweden.
- 24. Defendants Martin and Ekman will be referred to herein as the "Individual Defendants."
- 25. During the Class Period, the Individual Defendants, as senior executive officers and/or directors of Elan, were privy to confidential and proprietary non-public information concerning Elan via: their direct "hands on" involvement in Elan's business; access to internal corporate documents, conversations and connections with other corporate officers and employees; attendance at management and/or board of directors meetings and committees thereof; and reports and other information provided to them. Because of their possession of such information, the Individual Defendants knew or recklessly disregarded that the adverse facts specified herein were misrepresented and/or had not been disclosed to, and were being concealed from, the investing public.

- 26. The Individual Defendants are liable as direct participants in the wrongs complained of herein. In addition, the Individual Defendants, by reason of their status as senior executive officers and/or directors, were "controlling persons" within the meaning of Section 20(a) of the Exchange Act and had the power and influence to cause the Company to engage in the unlawful conduct complained of herein. Because of their positions of control, the Individual Defendants were able to and did, directly or indirectly, control the conduct of Elan's business.
- 27. The Individual Defendants, because of their positions with the Company, controlled and/or possessed the authority to control the contents of Elan's reports, press releases and presentations to securities analysts and the investing public. The Individual Defendants were provided with copies of Elan's misleading reports and press releases prior to or shortly after their issuance, and had the ability and opportunity to prevent their issuance or cause them to be corrected.
- 28. As senior executive officers and/or directors and as controlling persons of a publicly traded company governed by the federal securities laws, the Individual Defendants had a duty to promptly disseminate accurate and truthful information, and to correct any previously issued statements that had become materially misleading or untrue, so that the price of Elan ADRs would be based upon truthful and accurate information. The Individual Defendants' misrepresentations and omissions during the Class Period violated these obligations.
- 29. The Individual Defendants are liable as participants in the fraudulent scheme and course of conduct which operated as a fraud or deceit on purchasers of Elan's call options by disseminating materially false and misleading statements and/or concealing material adverse facts. The scheme deceived the investing public regarding the intrinsic value of Elan's call options and caused Plaintiff and other members of the Class to purchase Elan's call options at artificially inflated prices, and to suffer significant economic losses when the truth was revealed.

BACKGROUND

- 30. More than five million people in the United States currently suffer from Alzheimer's disease, and the incidence of the disease is increasing. There are drugs that have been approved by the FDA for the treatment of Alzheimer's, but they are not very effective because they treat the symptoms of Alzheimer's (loss of cognition and function) for only a short time. Nevertheless, those drugs produce \$4 billion in annual U.S. sales. Therefore, the market for an Alzheimer's drug is believed to amount to as much as tens of billions of dollars annually.
- 31. The usual clinical trial programs for a pharmaceutical product consist of three sequential phases of clinical trials. The first phase is a small phase 1 trial to test the safety of the product. In the second phase of testing, different dosages of the product are tested to determine the efficacy, and to test the safety of the product on the target patient population, to ascertain the most effective dosage, and to develop other data regarding the drug. Data from a phase 2 clinical trial or clinical trials are normally used to design the third and final phase of clinical trials. Moreover, a dose effect, increased effectiveness with increased dose, is considered evidence of efficacy by the FDA, and dose comparisons are a specified form of controlled trials in FDA regulations. The third and final phase of clinical trials normally proceeds only if the phase 2 trial or trials provide adequate evidence of efficacy and safety of a pharmaceutical product.
- 32. For more than eight years, Elan and Wyeth's Alzheimer's Immunotherapy Program actively pursued treatments without any commercial success. By 2006, bapineuzumab, an experimental humanized monoclonal antibody for the treatment of mild to moderate Alzheimer's disease, was the most promising compound being developed by Wyeth and Elan through their Alzheimer's Immunotherapy Program. Both Wyeth and Elan bet hundreds of millions of dollars on bapineuzumab's success, most of which was poured into costly clinical research and development programs. Achieving success with bapineuzumab, however, was contingent on FDA

approval which, in turn, was hinged on the drug's successful performance in clinical trials providing the drug was safe and effective for use.

- 33. As part of that program, Elan and Wyeth conducted the Phase 2 Trial, an 18-month clinical trial of bapineuzumab, at approximately 26 research centers throughout the U.S. The 240 patient Phase 2 Trial of bapineuzumab was a randomized double-blind, placebo controlled, multiple ascending dose study with four dose cohorts. Each participant in the study took bapineuzumab or a placebo for 18 months. Because patients enrolled in the Phase 2 Trial on a rolling basis, the trial, which was initiated in April 2005, was not completed until April 2008.
- 34. The Phase 2 Trial was designed to measure the efficacy of the drug compared to placebo using a number of different tests. The two primary tests were the ADAS-Cog¹ and the Disability Assessment Scale for Dementia ("DAD"). If bapineuzumab performed statistically significantly better than placebo pursuant to these two tests, then, and only then, the trial would have met its "primary endpoint" and could support a claim that bapineuzumab is demonstrably effective. The Phase 2 Trial also included, as additional tests, changes in cerebral spinal fluid, changes in brain volume, the Neuropsychological Test Battery, Clinical Dementia Rating Sum of Boxes, and mini-mental state examination ("MMSE").
- 35. After discovering the disappointing results of the Phase 2 Trial that ended in April 2008, Defendants attempted to conceal, and did conceal, the negative information from investors for as long as possible. Unfortunately for Defendants, investors and analysts were expecting the results in the summer of 2008 and analysts were already discussing that the results of the Phase 2

10

_

¹ The ADAS-cog test "is the most widely recognized and utilized measure of cognition in Alzheimer's drug trials. All four Alzheimer's drugs currently on the market used the ADAS-cog test as the endpoint of their phase III trials." *See* http://www.pharmalot.com/2008/02/forgetting-the-rules-wyeth-elan-alzheimers/.

Trial may be disappointing.

36. For example, on April 21, 2008, *Forbes Magazine* published an article entitled, "Attacking Alzheimer's," which stated, in relevant part, the following:

But by focusing so heavily on amyloid, the drug industry is taking a big risk. Even after decades of research, the case that amyloid buildup is the main cause of the disease is hardly airtight. Studies have found that some people who die from other diseases, with no dementia, still have amyloid in their brains.

The trials "are based largely on theory and hope--and some rather considerable business considerations," says University of Southern California psychiatrist Lon Schneider, a consultant to several companies. "None of the drugs have shown evidence of efficacy yet." Geneticist John Hardy, one of the first to finger amyloid as a suspect, puts the odds at 50-50 that one of the anti-amyloid drugs will work. "We are all on tenterhooks," he says.

Some researchers argue that amyloid is one of many factors in the disease and may not be the primary one for most people. "We may get rid of plaques, but it may not do anything," says John Trojanowski of the University of Pennsylvania.

* * *

Myriad will wrap up its final-stage trial any month now. *Even more intensely awaited* are the results of a second-stage trial of Wyeth's antibody, bapineuzumab. Both companies may reveal results this summer. Says Khachaturian, "If these trials work, it will open the floodgates. If they don't, we are back to square one."²

37. On June 13, 2008, *TheStreet.com* published an article entitled "Biotech Watch: Elan's Alzheimer's Drug Data," which stated, in part, the following:

The current stock prices of both companies, most certainly Elan, to some extent already bakes in positive phase II results and the start of the phase III studies. I'd be cautious in saying that, historically, the bar is low for moving Alzheimer's drugs into phase III studies, which has led, so far, to a very high failure rate. It appears investors are expecting a lot from this bapineuzumab phase II study, and it's far from certain that the results will be as conclusive or positive as many Elan bulls believe they're going to be.

* * *

Aha, now you're delving into the complexities and controversies of Alzheimer's research. *Not all scientists believe that the "beta amyloid hypothesis" is the cause of Alzheimer's*. Some researchers believe these protein clumps are just a side effect

-

² Emphasis in bold/italics added unless otherwise noted.

of the disease, so that clearing them from the brain won't improve a patient's cognitive or functional ability.

Elan and Wyeth are expected to present some data showing whether or not bapineuzumab does reduce the level of beta amyloid in the body, but that unto itself, is not enough for approval.

* * *

Frankly, I have no idea because it depends on what the bapineuzumab data show us. Have I been a skeptic? Yes, that's a fair assessment, especially since I do believe that Elan's efforts to push the NTB cognitive test suggests that bapineuzumab is not having the desired effect using the ADAS-cog, which I consider crucial.

With that said, Elan, in particular, is a battleground stock with both bulls and bears in no mood to give up the fight anytime soon. The phase III studies won't be completed for two years. It won't surprise me if Elan and Wyeth have something positive to say about bapineuzumab's phase II study in their joint press release, but the real important details are more likely to see the light of day at the ICAD meeting.

38. Also, on June 16, 2008, *Boston.com* published an article entitled "Analyst awaits data on Wyeth-Elan Alzheimer's drug," which stated, in part, the following:

[Ian] Sanderson (analyst from Boston) thinks the phase II trial is going to be modestly disappointing. It's too small and uses too many different doses to achieve its main goal, he said...

39. Accordingly, not able to stall any longer, Defendants scheduled a presentation of the results of the Phase 2 Trial at the ICAD Conference. However, weeks before the full study results were to be disclosed at the ICAD Conference, due to analysts' comments that the results may be disappointing, Defendants decided to announce the positive ApoE4 non-carrier results first, giving investors and analysts several weeks to consider the value of a potentially effective Alzheimer's drug for ApoE4 non-carriers and lessen the impact of the negative results of the Phase 2 Trial that were already known to Defendants and were to be presented at the ICAD Conference.

FALSE AND MISLEADING STATEMENTS DURING THE CLASS PERIOD

40. On June 17, 2008, Elan and Wyeth issued a press release, which announced "Encouraging Top-line Results from Phase 2 Clinical Trial of Bapineuzumab for Alzheimer's Disease." Although the press release stated that the study "did not attain statistical significance on the primary efficacy endpoints in the overall study population," the June 17, 2008 press release stated that there were "statistically significant and clinically meaningful benefits in the patients in the study who did not carry the gene that increases the risk of having Alzheimer's disease." According to the press release, these non-carriers are estimated to compromise 40-70% of the Alzheimer's disease population. The press release stated as follows:

Elan Corporation, plc and Wyeth today announced *encouraging preliminary findings from a Phase 2 study of bapineuzumab* (AAB-001) in patients with mild to moderate Alzheimer's disease. In the 18-month trial, bapineuzumab appeared to have clinical activity in treating Alzheimer's disease.

Efficacy Findings

The study did not attain statistical significance on the primary efficacy endpoints in the overall study population. *Post-hoc analyses did show statistically significant and clinically meaningful benefits in important subgroups.*

In non-carriers of the Apolipoprotein E4 (ApoE4) allele, estimated in the literature to be from 40 to 70 percent of the Alzheimer's disease population, post-hoc analyses *showed statistically significant and clinically meaningful benefits* associated with bapineuzumab treatment on several key efficacy endpoints, including the Alzheimer's Disease Assessment Scale (ADAS-cog), the Neuropsychological Test Battery (NTB), the Mini Mental State Examination (MMSE) and the Clinical Dementia Rating — Sum of Boxes (CDR-SB). A favorable directional change was seen on the Disability Assessment Scale for Dementia (DAD), although this was not statistically significant.

* * *

Safety Findings

As expected given the nature of the population studied, adverse events were very common in both placebo and bapineuzumab-treated patients. In non-carriers, the number of patients experiencing serious adverse events was similar between placebo and bapineuzumab-treated patients. In carriers, serious adverse events were

more frequently observed in bapineuzumab-treated patients than in placebo patients. In addition, vasogenic edema was reported in the treated population with an increased frequency in carriers and at higher doses. No cases were reported in placebo patients. In the ongoing Phase 3 studies, carriers of the ApoE4 allele are being treated with a lower dose to minimize the risk of vasogenic edema. *The Companies believe that the overall safety findings from this Phase 2 trial support their prior decision to move to Phase 3 studies*.

CEO Comments

"The preliminary analyses of the Phase 2 study are a continued validation of the amyloid approach to Alzheimer's disease and an important milestone in our companies' ongoing commitment to bring new treatment options to patients," said Kelly Martin, President and CEO of Elan. "These results clinically support our decision to move into Phase 3 last year."

* * *

These findings reflect preliminary analyses of the Phase 2 data and its implications for ongoing clinical development of bapineuzumab. In this trial, there were imbalances in patient numbers and characteristics at baseline between subgroups studied that may or may not have affected these results. Further analysis will continue in advance of a planned scientific presentation of detailed results of this study at the International Conference on Alzheimer's Disease (ICAD) in Chicago, July 29, 2008.

- 41. As a result of these statements, the price of Elan ADRs rose from \$27.11 to \$30 in one day, an increase of over 10%. By July 10, 2008, Elan ADRs were trading at over \$36, more than 120% higher than they traded prior to the Class Period.
- 42. Defendants' June 17, 2008 press release was materially false and misleading because it failed to disclose the known, materially adverse results of the Phase 2 Trial. Specifically, Defendants failed to disclose that:
- (a) The Phase 2 Trial showed no dose response, meaning that taking higher doses of bapineuzumab did not correlate with greater improvement in symptoms;
- (b) Among the subset of patients in which some evidence of bapineuzumab's efficacy was purportedly found, the patients taking placebo showed a larger than expected cognitive decline. If the placebo group deteriorated more rapidly than average patients, this would

exaggerate the efficacy results of bapineuzumab in the study;

- (c) In order to manufacture bapineuzumab's statistically significant outperformance of placebo in the Phase 2 Study, Defendants changed the statistical model *post hoc* from linear to curvilinear. The original trial protocol called for linear modeling. Had Defendants not changed to a curvilinear model without informing investors, they could not have claimed that bapineuzumab outperformed placebo by a statistically significant margin, even in the ApoE4 non-carrier group;
- (d) Although the Phase 2 Trial showed bapineuzumab to outperform placebo in a subset of the patient population over 18 months, there was no short-term advantage for bapineuzumab;
- (e) Using the MMSE, which Defendants characterized as a "key measure of cognitive function," there was no significant signal in the Phase 2 Trial that bapineuzumab was more efficient than the placebo;
- (f) Nearly 10% of the patients in the Phase 2 Trial (12 patients) taking bapineuzumab developed vasogenic edema versus zero patients in the placebo group (three of the patients affected also developed "micro bleeds" in their brains);
- (g) Three deaths were reported in the group taking bapineuzumab compared to none in the placebo group. One of the deaths was caused in part by an aortic dissection (a tear in the wall of this major artery) which has the potential to be related to drugs such as bapineuzumab;
- (h) There were nine additional adverse effects that occurred two or more times as often in patients taking bapineuzumab versus placebo and in more than 5% of such patients, including, anxiety, vomiting, hypertension, paranoia, skin laceration, gait disturbance, and muscle spasms; and
- (i) Bapineuzumab not only failed to show a statistically significant benefit compared to placebo per the original trial protocol, but failed to do so by a large margin.

- 43. On June 17, 2008, *Credit Suisse* published an analyst report entitled "Key Alzheimer's data read encouraging," which stated in part:
 - The eagerly awaited data for AAB-001 (bapineuzumab) came with some encouraging indications of efficacy this morning, with the company reporting a statistical benefit after 18 months in a subgroup that does not carry the APOE4 gene (around 50% of mild to moderate AD patients). . .
 - Although this is a small trial and the post hoc subgroup statistical analysis is weaker than prospectively defined statistically analysis, some investors may gain more confidence that the effects of AAB-001 on cognition seem robust. This is because reported statistical benefits on cognition in the APOE4 non- carrier group were replicated in three independent and validated cognitive tests (ADAS-cog, NTB, and MMSE). . . .
- 44. On June 17, 2008, *Natixis Bleichroeder* published an analyst report entitled "ELN: No Negative Babby Data Keeps Us Happy," which stated in part:

The long-awaited Phase II bapineuzumab data were unleashed in a press release early this morning, and although the release contained scant numbers, the data were very encouraging.

45. On June 18, 2008, *Davy Research* published an analyst report entitled "Bapineuzumab provides better-than-expected subset data: risked valuation upgraded to \$31." The report stated in part:

Becoming more confident on development and commercial prospects for Bapineuzumab

- The top-line Phase II data on Bapineuzumab were better than our expectations given what look to be robust efficacy results in the ApoE4 non-carrier group.
- Increased confidence in the development prospects and commercial potential for the drug lead us to upgrade our risked valuation to \$31 (range \$27-\$32). Our models suggest unrisked upside to approximately \$42, based on a \$4.5bn peak revenue potential in AD [Alzheimer's Disease].

Encouraging efficacy, consistent safety

* * *

Full data provision at ICAD will allow us to answer several more pertinent questions, chief among which are the following:

- What is the nature and trend of response across dose strengths?
- 46. As reported by the *International Business Times*, on June 23, 2008, following Elan's and Wyeth's representations about the Phase 2 trial results, a Goldman Sachs analyst rated Elan's stock a conviction buy, and raised his price target to \$45 per share from \$34.20.
- 47. On July 8, 2008, *Cowen and Company* published an analyst report entitled "Bapineuzumab Could Be A Breakthrough . . . But Several Hurdles Remain" and reported that "*Bapineuzumab Phase II Results Exceeded Expectations*."
- 48. On July 24, 2008, *Stanford Group Company* published an analyst report entitled "ELN: More questions to be answered at ICAD," which stated in part:
 - Bapineuzumab Phase 3 US studies on track to complete patient enrollment in 2008. Launched in Dec 2007, these two large 18-month trials (n=800; n=1,250) are enrolling well and the company expects to complete enrollment by the end of the year. Wyeth [] is six months behind in patient enrollment (mid-09 complete) for two international Phase 3 studies of Bapineuzumab (over 2,000 patients).

* * *

10 key questions we expect to be answered at ICAD:

* * *

- 3. Is there dose response in efficacy endpoints?
- 4. Time effect of Bapineuzumab time of effect onset, curve separation over time, and rate of decline?
- 49. On July 25, 2008, *Natixis Bleichroeder* published an analyst report which stated, in part:

The full bapineuzumab results will be shown during a 15-minute presentation at ICAD in Chicago on Tuesday, July 29.

* * *

Key items we are looking for that would allow the stock to continue to work include: . . . *Early* and continuing separation of the curves over time — this will dictate the potential filing prior to the end of the 18-month endpoint, after a possible interim efficacy look *A clear dose response* . . .

50. On July 25, 2008, *Cowen and Company* published an analyst report entitled "Raising Tysabri Outlook Post Solid Q2 Results, But It's All About Bap." The report stated in part:

Elan's Q2 revenues came through ahead of our and the Street's expectations, driven by better Tysabri trends. . . . But *bapineuzumab is the stock-moving issue*

51. On July 28, 2008, *Cowen and Company* published an analyst report entitled "What To Look For In Tomorrow's Bapineuzumab Phase II Data Presentation," which stated in part:

The Phase II data for ELN/WYE's bapineuzumab (Mab for Alzheimer's) will be presented tomorrow afternoon at the International Conference on Alzheimer's Disease (ICAD).

* * *

1. The relative efficacy curves: The most important indicators of bapineuzumab's efficacy signal will be graphs of drug-placebo differences in change from baseline scores on cognitive measures (ADAS-cog and/or NTB) in combination with the global measure (CDR-sb). Early and sustained cognitive improvement — at least relative to the placebo decline (absolute improvement relative to baseline would be a bonus) is key to supporting a signal for bapineuzumab efficacy.

Elan and Wyeth released brief top-line results from the bapineuzumab Phase H trial on June 17th. . . . Assuming a 6.5 point decline on the ADAS-cog score for the placebo group over 18 months, a 57-63% relative effect size for the bapineuzumab group translates to a 3.7-4.1 point spread vs. placebo (i.e. a 2.4-2.8 point absolute decline at 18 months). . .

THE TRUTH EMERGES

52. On July 29, 2008, Elan and Wyeth jointly issued a press release, announcing that they would be presenting the Phase 2 Trial results at the ICAD Conference. The press release stated, in part, the following:

Elan Corporation, plc and Wyeth today are presenting detailed results from the companies' 18-month Phase 2 study of bapineuzumab (AAB-001) in patients with

mild to moderate Alzheimer's disease at the Alzheimer's Association's International Conference on Alzheimer's Disease 2008 in Chicago, Illinois. As previously announced, in the study, bapineuzumab appeared to have an acceptable safety profile and clinical activity in treating Alzheimer's disease. *Potential efficacy signals were seen at a range of doses without a clear dose response. The study did not attain statistical significance on the pre-specified efficacy endpoints in the overall study population.* Post-hoc analyses showed statistically significant and clinically meaningful benefits in important subgroups.

* * *

Phase 3 Program Implications

The Phase 2 data reinforce the design of the ongoing Phase 3 studies by ApoE4 carrier and non-carrier populations and the selected dose groups. The companies plan to continue all four ongoing Phase 3 studies. The ApoE4 carrier dose in the Phase 3 trials was selected to seek to minimize the risk of VE observed in the Phase 2 trial. The companies intend to obtain feedback from regulatory authorities in the coming months to finalize parameters for the Phase 3 program and discuss and reach agreement on requirements for registration.

53. Also on July 29, 2008, around 6 p.m., on a live webcast hosted by Elan and Wyeth, additional, negative, information was disclosed:

Tim Anderson — Sanford C. Bernstein & Company, Inc. — Analyst:

Thank you. The company press release doesn't mention bleeding episodes, yet a press interview with someone in clinical development at Wyeth says there were three or four bleeds, which seems like it could be important, given how the drug works. I'm hoping you could characterize those patients better in terms of two things, ApoE4 carrier status and also the dose of drug that they received.

Chris Burns — Elan Corporation, PLC — SVP, Global IR:

Thanks, Tim. Dr. Black, perhaps comment on that.

Ron Black — Wyeth Research — Assistant VP Neuroscience:

Sure. I think when we talk about bleeding in particular, we need to distinguish what we're talking about here in this population. So these are microbleeds and these typically occur in Alzheimer patients and are asymptomatic, and in all the patients after every dose we do a type of MRI scan called a T2 Star MRI scan, which is very sensitive in detecting these microbleeds. Now in other population studies of Alzheimer's disease patients in which T2 Star scans are done, reports of up to 20% in the population of Alzheimer's disease — the microbleeds have been reported in up to 20% of Alzheimer's patients. *In this case, we saw some*

of these microbleeds in patients with vasogenic edema. There were three of the patients out of the 12 with vasogenic edema who had these tiny little areas of microbleeding which you can only detect on this specific MRI sequence, and those patients — they didn't appear to be of any clinical consequence.

* * *

Catherine Arnold — Credit Suisse — Analyst

Thanks for the follow-up. I wanted to ask you about the MMSE. Obviously you did point out the difference in the non-carrier group in terms of placebo and bapi. But I was wondering what happened to MMSE particularly in that group. And if you have any other comments for the trial overall, we didn't get to see that. Thanks.

Chris Burns — Elan Corporation, PLC — SVP, Global IR

Thanks. I think Allison, can you comment on that to some degree, or Dr. Gilman I think had some thoughts on that.

Sid Gilman — University of Michigan — Chair of Bapineuzumab Safety Monitoring Committee

We did evaluate MMSE throughout the trial. We didn't see a significant signal through the 78 weeks with MMSE, but MMSE is not a particularly great test vehicle for pharmaceutical evaluation. It's good to evaluate the level of dementia initially, but not to follow patients because of learning that can take place with it. There were signals but they were not particularly strong signals.

- 54. With the webcast, Defendants presented a series of slides to investors³ that included the following disclosure of adverse events identified in the Phase 2 Trial:
 - [Adverse Events] occurring ≥2 times as often as placebo rate and seen in >5% of bapineuzumab patients

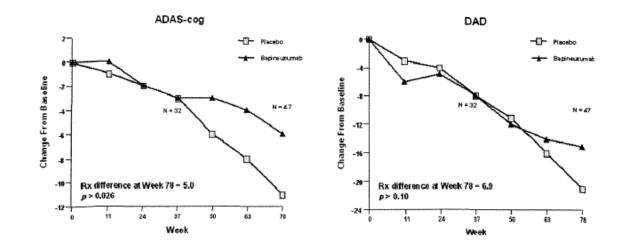
Back pain	12.1% vs 5.5%	Weight loss	6.5% vs 1.8%
Anxiety	11.3% vs 3.6%	Paranoia	6.5% vs 0.9%
Vomiting	9.7% vs 3.6%	Skin laceration	5.6% vs 2.7%
VE (vasogenic edema) 9.7% vs 0%		Gait disturbance	5.6% vs 1.8%
Hypertension	8.1% vs 3.6%	Muscle spasms	5.6% vs 0.9%

55. The slides also included the following charts showing bapineuzumab's performance

20

³ Following the live webcast, an archived version of the webcast, including the slides, was made available on both Elan's and Wyeth's websites.

compared to placebo over time using the two principle tests, ADAS-Cog and DAD:



- 56. As a result of the press release, the presentation at the ICAD Conference, and the webcast on July 29, 2008, investors learned for the first time that:
- (a) The Phase 2 Trial showed no dose response, *i.e.*, taking higher doses of bapineuzumab did not correlate with greater improvement in symptoms. Indeed, patients did not even show a consistent pattern of benefit across the four different dosages that were administered in the trial. The absence of a dose response suggested that any improvement seen on bapineuzumab compared to placebo was random.
- (b) Among ApoE4 non-carriers in the Phase 2 Trial, the group in which some evidence of bapineuzumab's efficacy was purportedly found, the patients taking placebo showed a larger than expected cognitive decline. Specifically, the ADAS-Cog scores of this group of patients (21 in all) dropped 11 points over the 78-week period of the trial, compared with a 7 point loss of cognition by placebo patients in a much larger trial recorded publicly, and lower rates in other 18-month trials, which suggests that the condition of the placebo patients may have been more severe than the norm in such trials. This was considered quite a dramatic decline by other scientists and physicians working in Alzheimer's disease clinical trials. On average, they would have expected

an ADAS-Cog decline of six to nine points among those taking placebo. To the extent the placebo group deteriorated more rapidly than average patients, it exaggerated the efficacy results of bapineuzumab in the Phase 2 Trial;

- (c) In order to manufacture bapineuzumab's statistically significant outperformance of placebo in the Phase 2 Trial, Defendants changed the statistical model *post hoc* from linear to curvilinear. The original trial protocol called for linear modeling. Had Defendants not changed to a curvilinear model without informing investors, they could not have claimed that bapineuzumab outperformed placebo by a statistically significant margin, even in the ApoE4 non-carrier group;
- in a phase 1 trial ("Phase 1 Trial"), it was reported that bapineuzumab began outperforming placebo at 16 weeks. Measured using the two primary tests the Phase 2 Trial was designed to rely upon, bapineuzumab performed no better than placebo until well into the trial. Using the first such test, the DAD, patients taking bapineuzumab showed no improvement over placebo until 63 weeks into the 78-week study. Similarly, using the ADAS-Cog, patients taking bapineuzumab showed no improvement over placebo until 50 weeks into the 78-week study;
- (e) Using the MMSE, which was a tertiary test, but which Defendants characterized as a "key measure of cognitive function," there was no significant signal that bapineuzumab worked better than placebo in the Phase 2 Trial. The MMSE was the only test under which bapineuzumab was reported to have performed significantly better than placebo in Elan's Phase 1 Trial;
- (f) Nearly 10% of patients taking bapinezumab in the Phase 2 Trial (12 patients) developed vasogenic edema versus zero patients in the placebo group. This condition was detected only by subjecting patients to numerous MRI scans. In the real world, Alzheimer's patients would not be monitored this closely, so that vasogenic edema remains an issue with respect to the drug. Additionally, three of the bapineuzumab patients so affected also developed

"micro bleeds" in their brains;

- (g) Three deaths were reported in the group taking bapineuzumab compared to none in the placebo group. One of the deaths was caused in part by an aortic dissection (a tear in the wall of this major artery) which has the potential to be related to drugs such as bapineuzumab;
- (h) There were nine additional adverse effects that occurred two or more times as often in patients taking bapineuzumab and in more than 5% of such patients, including back pain, anxiety, vomiting, hypertension, weight loss, paranoia, skin laceration, gait disturbance, and muscle spasms; and
- (i) Bapineuzumab not only failed to show a statistically significant benefit compared to placebo per the original trial protocol, but failed to do so by a large margin.
- 57. When the complete Phase 2 Trial results were finally disclosed on July 29, 2008, the price of Elan ADRs dropped 42% in one day. The adverse results of the Phase 2 Trial meant that the Phase 3 Trials would likely have to run their full 18-month courses before FDA approval would be possible. Thus, even if eventually approved by the FDA, any sales of bapineuzumab would not begin for many months, if not years, further into the future. This reduced the then-present value of bapineuzumab. Finally, the fully disclosed Phase 2 Trial data on July 29, 2008 suggested that bapineuzumab was unlikely to be greatly superior to Alzheimer's drugs already on the market, also limiting its commercial potential.
- 58. On July 30, 2008, Adam Feuerstein published an article on *TheStreet.com* entitled "Elan-Wyeth Alzheimer's Data Spook Bulls," which stated in part:
 - . . . Tuesday afternoon, we finally got to see the actual data from the bapineuzumab study and it was wildly inconsistent.

Let me give you one example: *There was absolutely no dose response with bapineuzumab in this trial.* Typically, you like to see increasingly higher doses of a drug correspond with improved efficacy. Instead, *what we saw from the bapineuzumab study just looked like so much randomness*, which in clinical trials

is definitely not a good thing.

* * *

The ApoE4 non-carrier group of patients was Elan and Wyeth's best shot at making a convincing case for bapineuzumab, but once again, the details in the data Tuesday — stuff not available [to investors] in June — tripped them up.

When you look at the actual performance curves of the study, bapineuzumab-treated patients reported a 5-point improvement over placebo on the ADAS-cog test, a measure of cognition and a co-primary endpoint of the study.

However, for nearly a year into the 18-month trial, the bapineuzumab and placebo patients were both losing cognition at the same rate. The benefit seen for bapineuzumab patients only came about because placebo patients suffered a steep loss of cognition at the very end of the study.

* * *

... [T]here is no good explanation for why bapineuzumab would take so long to be effective compared to placebo. The fact that the two ADAS-cog curves (bapineuzumab and placebo) were essentially identical for much of the first year of the study is a problem because most Elan "believers" thought the curves would separate early in bapineuzumab's favor and remain that way for the entire length of the study.

* * *

The loss of cognition by placebo patients totaled 11 points on the ADAS-cog scale at 18 months, far worse than is typically seen in other Alzheimer's studies of this duration.

For instance, the placebo patients in the large phase III study of Myriad Genetics' [MYGN — commentary — Cramer's Take] Flurizan reported a 7-point loss of cognition on the ADAS-cog scale. These data, from a study much larger than Elan and Wyeth's phase II, were also presented Tuesday at the conference.

The concern here is that the improvement in cognitive function seen in the ApoE4 non-carriers is not a result of anything that bapineuzumab is doing, but is instead caused by poor-performing placebo patients from a small subset analysis.

* * *

Twelve patients in the study treated with bapineuzumab developed a potentially dangerous accumulation of fluid in the brain known as vasogenic edema. All of these cases resolved favorably however, and six of the patients were eventually able to continue treatment with bapineuzumab.

* * *

There is another side to this safety story, however. Researchers were only able to detect the vasogenic edema by subjecting patients to numerous (and expensive) MRI scans. In the real world, Alzheimer's patients will never be monitored this closely, so what happens if vasogenic edema goes undiagnosed and untreated in bapineuzumab patients?

Other safety issues: Several instances of bapineuzumab patients experiencing "micro-bleeds" in their brains, plus higher rates of seizures and psychiatric events.

59. On July 30, 2008, *Caris & Company* published an analyst report which stated in part:

Reality Check for Phase II Bappy Data Investors and analysts finally got to see real data behind the Phase II bapineuzumab study conducted by Elan and partner, Wyeth (3*/Average) at the International Conference on Alzheimer's Disease (ICAD) meeting yesterday. . . [E]nough information was revealed to suggest that the Phase II results could be completely invalid. In particular, no dose response, a placebo arm that behaved much worse than expected, and a contrived statistical methodology are the major criticisms of the data, in our view, which lead to our conclusion that the results previously released may not be valid after all. . . . [T]he statistical significance seen in the non carrier group using the ADAS-Cog scale was achieved against a placebo group that had an 11 point score decline. Based on our analysis, typical placebo groups would have declines in the 6-7 point range, which actually was the decline seen in the bapineuzumab-treated non-carrier patients. . . . Safety issues remain. The company reported 12 cases of vasogenic edema, with two in the treated APO-E4 non-carrier group. In addition, 3-4 incidences of micro-bleeds and 3 deaths occurred in bapineuzumab-treated patients...

60. On July 30, 2008, *Cowen and Company* published an analyst report which stated in part:

The presentation of the detailed bapineuzumab Phase II data yesterday at the ICAD meetings raised unexpected questions about the robustness of bapineuzumab's apparent efficacy — and about the chances for success...

[T]he variability of the data, the lack of a dose-response, and the unusually sharp ADAS-cog decline in the placebo group all erode the strength of the efficacy signal... With lower conviction in Phase III success for bapineuzumab and at least two years to wait for confirmation, we have trimmed our estimated bapineuzumab value by \$4-5B, or \$10 per ELN share, reflecting a higher discount rate.

* * *

Elan was clipped . . . in after hours trading: we believe the raised risk profile of bapineuzumab reasonably trims \$4-5B (\$10/share) from the fair valuation. An early BLA filing and early visibility on Phase III now is unlikely.

61. Also on July 30, 2008, *Canaccord Adams* published an analyst report entitled "Bapineuzumab Disappoints," which stated in part:

Yesterday, Elan and development partner Wyeth reported less-thanspectacular Phase 2 data from their lead Alzheimer's disease drug bapineuzumab at the International Conference on Alzheimer's Disease (ICAD) in Chicago.

Could I please get some more *post hoc* with my *post hoc* analysis?

* * *

. . . In a *post hoc* analysis, in addition to subdividing the treated population into ApoE4 carriers and non-carriers, the companies used a modified intent-to-treat (MITT) analysis that assumed non-linearity in the data. While a *post hoc* modification to the analysis such as this could reveal interesting facets of the clinical data, we cannot believe that it could be conclusively supportive of the efficacy of bapineuzumab in Alzheimer's disease.

* * *

Of particular concern for us from the data presented was *the obvious lack of* a dose response across patient groups. Although the companies attempted to explain the differences across the doses, we believe that the varying clinical responses on different endpoints are concerning. . . .

62. On July 30, 2008, *Stanford Group Company* also published an analyst report which stated in part:

Bapineuzumab Phase 2 data fails to meet high expectations

- Key issues that compounded the Phase 2 efficacy data: 1) the placebo arm performs worse in the ApoE non-carrier (ADAS-cog=-11 at 18 month vs. -7 or -8 points on average); 2) unexpected non-linear decline in placebo arm; 3) lack of dose-response.
- Safety signals seen also increase risks of Phase 3 studies. 3 deaths occurred in the Bapi treatment arm (vs. 0 in placebo), adverse events seen double in Bapi treatment arm than placebo include back pain, anxiety, vomiting, vasogenic

edema, hypertension.

- The underwhelming data makes accelerated FDA filing on interim analysis unlikely. . . .
- ... We lowered our estimate for likelihood of Phase 3 success from prior 75% to 50% and our price target from \$28/sh to \$25/share.
- 63. On July 31, 2008, *Credit Suisse* published an analyst report which stated, in part:

. . . like the market, we remain disappointed in the lack of dose response in this data and the confusion surrounding the analysis conducted.

* * *

• The move transition from a linear analysis to a non linear analysis for the Post Hoc analysis weakens findings

Credit Suisse:— We agree that this transition was not communicated well to the market. . . .

64. On July 31, 2008, *NCB Stockbrokers Ltd.* published an analyst report entitled "Update to Bapineuzumab Valuation; Target Price Reduced to \$22.40," which stated in part:

Efficacy: It has been known since the release of the top line results in June that the ApoE4 non-carrier group demonstrated statistically significant benefits. The additional detail provided at ICAD showed an ADAS-cog difference of +5 points (versus placebo), however this result was on the basis of comparison with an 11 point decline in the placebo group (versus a 6 point decline in the treated group). An 11 point decline is considered to be at the upper end of expected range for non-treated (placebo) patients and somewhat undermines the veracity of the statistically significant results.

* * *

Dosage — . . . there was no clear dose response evident.

In light of these details which undermine the case for disease modifying efficacy, point to more pronounced safety questions, and push out any likely commercialization date we have reduced our NPV for bapineuzumab from \$8.1 bn to \$3.4bn.

65. On August 1, 2008, *TheStreet.com* published an article entitled "Feuerstein's Biotech-Stock Mailbag: Elan," which stated in part:

Is there any compelling reason to own Elan now? Bapineuzumab looks like a crapshoot at best, and news flow around the program goes dark as the phase III studies enroll patients and we wait two years for data. Many bulls were hoping for an early or accelerated approval filing. Please, *the bapineuzumab data are so weak, that rosy scenario is now pure fantasy.*

* * *

More on Elan from Stanley W. [one of Mr. Feuerstein's readers] who wrote:

I don't understand how Kelly Martin could be so bullish on bapineuzumab based on this data. Did he mislead us all?"

Kelly Martin, Elan's CEO, has a BIG credibility problem with Wall Street. Without naming names, let's just say that I saw a couple of Elan's largest institutional shareholders at the ICAD conference Tuesday night, and they looked like they wanted to take Martin into an alley and, well, you get the idea.

In an interview with *CNBC* Wednesday morning, Martin tried to blame Elan's selloff on too-high expectations and investors who want simple answers to complex questions.

That's laughable. *It was Martin, himself; who set those high expectations for bapineuzumab,* and the data aren't difficult at all to understand.

66. On August 1, 2008, the *Irish Independent* stated:

Over EUR3bn has been slashed off Elan's market capitalisation since Tuesday, when the drugmaker announced disappointing data on its Alzheimer's Disease treatment Bapineuzumab

- 67. On August 4, 2008, *Cowen and Company* published an analyst report entitled "ELN Has Longer-Term Value, But Debt Overhang Likely Keeps A Lid On Shares," which stated in part:
 - (3) The disappointing observation was that bapineuzumab's efficacy signal in the ApoE4 non-carriers was weakened enough by the high variability across doses and the unusually sharp cognitive decline in the placebo group that the 4,100-patient Phase III trial now is more of a proof-of-concept trial than a confirmatory efficacy and safety trial...
 - ... We now estimate bapineuzumab's 2015 global sales at \$6.0B, based on 28% penetration of the estimated treated ApoE4 non-carrier AD patients with mild/moderate disease in the U.S. and 20% penetration of the similar patient population outside the US (versus 25-35% previously). We have increased the

discount rate we apply in valuating the bapineuzumab revenue stream to Elan (Wyeth and Elan split the bapineuzumab costs and potential revenues 50/50) from 20% to 35%, reflecting the higher risk profile of the ongoing Phase III program. The result: we now estimate the present value of the bapineuzumab program to Elan at \$2.6B, or \$5-6 per share, down from \$8.4B, or \$17-18 per share, prior to the presentation of the Phase II data.

POST-CLASS PERIOD EVENTS

68. On October 22, 2008, Wyeth disclosed, in a conference call, that European regulators had asked that European trials of bapineuzumab be delayed following the disappointing results of the Phase 2 Trial:

David Risinger - Merrill Lynch:

Yes thanks very much. You had mentioned that with respect to bapineuzumab in Europe you're engaging in meetings with regulatory authorities before they permit enrollment and/or permit continued dosing. Can you explain what changed to slow enrolment relative to your original expectations several months ago? And then just a quick second question that I'd like to slide in, can you just explain the FX benefit to EPS? Thank you.

* * *

Joseph M. Mahady - Senior Vice President and President:

David, very, very short, bapineuzumab in Europe was always projected to be running behind in terms of the U.S. study start date and June was when we just began to enroll certain centers and certain countries with the information that broke with the Phase II data and publicity around it in the ensuing weeks and months we began to get request from individual countries to review the full Phase II data, to review the Phase III protocols, any protocol amendments that had been implemented and then that has been going on for the past few weeks. . . . As a consequence in places where and in many places we had yet to begin enrollment, they had asked that enrolment not begin until they completed that review, in a couple countries where enrollment had just begun, they had asked us to hold until they finished this review. Those meetings and those submissions are ongoing as we speak and hope to have better understanding of where we are. But I think your insight is correct. We really are little behind where we would like to be in getting the full European program up and running. Thanks. . . .

69. Immediately following the disclosure of the delay in the Phase 3 studies, *Cowen and Company* published an October 23, 2008 analyst report which stated, in part:

Wyeth management disclosed yesterday that patient enrollment for the international segment of the bapineuzumab (Alzheimer's) Phase 3 clinical trials is running behind targets. ELN shares were hit by 13%+ on the disclosure, essentially removing bapineuzumab from the valuation.

* * *

- Wyeth: Bapineuzumab Ex-U.S. Phase 3 Enrollment Lagging. In a few countries where the bapineuzumab Phase 3 enrollment has not started or is very early, regulators have requested a review of the Phase 2 data. While no indication was given on the extent of the enrollment delay, we have delayed our enrollment completion target for the international trials by 3-6 months, to late '09.
- 70. On December 11, 2008, *TheStreet.com* published an article entitled "Elan's Martin Named Worst Biotech CEO of '08," explaining:

Martin . . . and his management team promised investors the sky and more when it came to Elan's experimental Alzheimer's disease drug bapineuzumab.

Unfortunately for Martin, the high expectations he set for the drug never materialized. As a result, Elan's share price fell through the floor, the company's investors lost a fortune and Martin's reputation and credibility were shattered.

Elan's stock price is down about 70% for the year and 80% from its high in early July, *right before the big bapineuzumab setback sent shares plunging, never to recover.*

71. On November 25, 2009, *Bioasis Technologies Inc.* published an article, entitled "Bapineuzumab's Phase II Results Published – AD Drug Fails Expectations," which stated, in part, the following:

Overall the study has not been successful. As the trial progressed, the researchers had to drop out patients with the Apo-E4 allele risk factor. Patients with this gene suffered from vasogenic edema (fluid leakage & accumulation) without experiencing any benefits from treatment. Later, the higher dose level of 2.0mg/kg was dropped as well, as fluid leakage was prominent among non-ApoE4 participants who received this dose. The gradual drop in patient population and dose levels has been disappointing.

The only positive sign that seems to be encouraging Elan and Wyeth to continue Phase III trials is that the drug works for a very small population who does not have the Apo-E4 risk factor. On comparison with Aricept (the best AD drug on the market), bapineuzumab seems to provide a 2-point advantage on the ADAS-COG

scale. But again, this positive sign comes from a post-hoc analysis of the data and is not as convincing to the scientific community.

72. On September 24, 2009, the SEC's New York Regional Office initiated an inquiry of Wyeth and Elan and subpoenaed records and information relating to the presentation of the Phase 2 Trial data for bapineuzumab at the International Conference of Alzheimer's Disease on the July 29, 2008.

ADDITIONAL SCIENTER ALLEGATIONS

- 73. During the Class Period, Defendants had knowledge of the misleading nature of the statements they made and acted in reckless disregard of the true information known and available to them at the time. In so doing, Defendants participated in a scheme to defraud and committed acts, practices, and participated in a course of business that operated as a fraud or deceit on purchasers of Elan's publicly traded call options during the Class Period.
- 74. Defendants knew the results of the Phase 2 Trial when they issued the June 17, 2008 press release, as the study was completed in April 2008 and the data from the Phase 2 Trial was available to Defendants. Once the study was completed in April 2008, the study was unblinded to analyze how bapuneuzumab had performed relative to the placebo. In fact, Defendants have conceded that they were fully aware of the Phase 2 Trial results by issuing a press release with the misleading results of the Phase 2 Trial on June 17, 2008. They could not have issued the press release without having reviewed the complete study results.
- 75. Further, Defendants are presumed to have knowledge of any information related to the development of bapineuzumab. First, Elan's and Wyeth's future hinged on the safety and effectiveness of bapineuzumab. According to analysts, bapineuzumab had the potential to be the "biggest drug of all time" and could have generated upwards of \$4-5 billion in revenue per year. Elan's total revenue in 2008 was approximately \$1 billion. Wyeth's total revenue in 2008 was

approximately \$22.8 billion.

- 76. Additionally, the success of bapineuzumab was especially important to Defendants in light of the problems Elan and Wyeth were facing prior to and during the Class Period. Elan's biggest selling drug, Tysabri, only came back to the market as of September 2006, after removal from the market in February 2005 following two deaths, and during the Class Period, sales were only slowly recovering. Further, Elan's other drugs' sales were also plummeting due to generic competition. Additionally, in 2007, Wyeth was just emerging from massive litigation related to two diet drugs, Redux and Pondimin, which had cost Wyeth a stunning \$21 billion. By late 2007 and early 2008, Wyeth was also struggling with patent issues related to two drugs, Effoxor and Protonix, that accounted for over a quarter of Wyeth's sales in 2007. In 2007, Wyeth also had widely publicized failures with several New Drug Applications before the FDA, including for an osteoporosis drug, a schizophrenic drug, and a menopause drug. Therefore, Elan and Wyeth attempted to mislead the investing public as long as possible regarding bapineuzumab to avoid more bad news.
- 77. In fact, Elan's Form 20-F annual report filed with the SEC on February 28, 2008, stated:

We have committed significant resources to the development and the commercialization of Tysabri and to the other potential products in our development pipeline (in particular, AAB-001 [bapineuzumab]).... If our Phase 2 and 3 clinical trials for AAB-001 [bapineuzumab] are not successfully completed, we will be materially and adversely affected.

78. Wyeth, in its Forms 10-K, for the fiscal years ended December 31, 2007 and December 31, 2008, also stated:

Successful development and commercialization of new pharmaceuticals, vaccines and biotechnology products is expensive and inherently uncertain. Conducting late-stage clinical trials, like our global Phase 3 program for our 13-valent pneumococcal conjugate vaccine and the Elan Corp. (Elan)-Wyeth global Phase 3 clinical program for bapineuzumab, is particularly costly. If our clinical trials are

not successful, we will not recover our substantial investments in the related product candidate. Even where our clinical trials are sufficient to obtain product approval, we may not be able to achieve our anticipated product labeling and profile, which could adversely impact the commercial success of the product. The substantial funds we spend developing new products depress near-term profitability with no assurance that the expenditures will generate future profits.

- 79. Moreover, at the latest by April 2008 and definitely before the June 17, 2008 press release, Defendants already knew that the Phase 2 Trial results showed that a higher dose of the drug was associated with vasogenic edema in patients that carried the ApoE4 gene. Also, Defendants knew that in carriers, serious adverse events were more frequently observed in bapineuzumab-treated patients than in placebo patients. These serious adverse effects, as well as which test group they occurred in, would have been immediately reported to Defendants. Further, Defendants knew that ApoE4 non-carriers seemed to perform better on bapineuzumab than carriers. Defendants admitted to their knowledge by stating, in the June 17, 2008 press release, that "[i]n the ongoing Phase 3 studies, carriers of the ApoE4 allele are being treated with a lower dose to minimize the risk of vasogenic edema." Defendants also conceded to their knowledge by designing the Phase 3 Trials (in December 2007) to separate the ApoE4 carriers from non-carriers and not using the 2.0 mg dose of bapineuzumab that had been associated with vasogenic edema in ApoE4 carriers.
- 80. Given the potential risk associated with the 2.0 mg dose and the acknowledged lack of evidence on any dose response theory, a 2.0 mg arm in the Phase 3 Trials for non-carriers should have been considered high risk and not justified in relation to potential benefit. Defendants finally admitted that there was a serious concern about the extended exposure of non-carriers to the 2.0 mg dose of bapineuzumab and discontinued the highest of three dosing regimens in the two ongoing Phase 3 Trials of bapineuzumab in patients with mild to moderate Alzheimer's disease who do not carry the ApoE4 gene.

81. On April 2, 2009, Elan and Wyeth issued a press release, entitled "Elan and Wyeth Plan to Amend Bapineuzumab Phase 3 Protocols," which stated, in part, as follows:

DUBLIN & COLLEGEVILLE, Pa.--(BUSINESS WIRE)--Apr. 2, 2009-- Elan Corporation, plc (NYSE: ELN) and Wyeth (NYSE: WYE) today announced that the companies will discontinue the highest of three dosing regimens, 2.0 mg/kg, in the two ongoing Phase 3 studies of bapineuzumab in patients with mild to moderate Alzheimer's disease (AD) who do not carry the Apolipoprotein E4 (ApoE4) allele (non-carriers). ApoE4 is a known genetic risk factor for development of AD. The 0.5 mg/kg and 1.0 mg/kg doses in these two trials will continue as planned.

* * *

The decision of the companies to discontinue the 2.0 mg/kg dose was made in concurrence with the study's independent Safety Monitoring Committee (SMC), following its review of vasogenic edema (VE) in the ongoing Phase 3 clinical program.

* * *

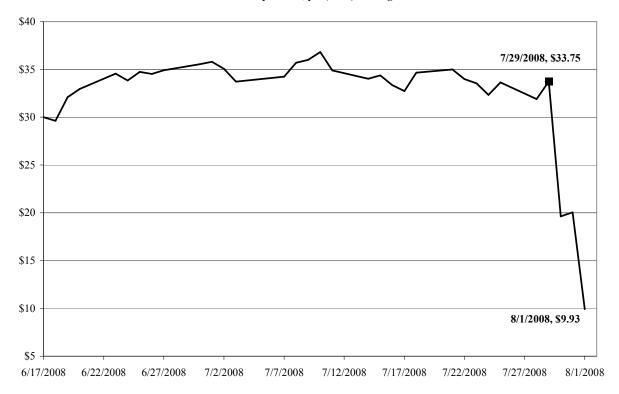
"Alzheimer's disease is a devastating condition and the development of new therapies that have the potential to slow progression of the illness is critical," said Elan President Carlos Paya, MD, PhD. "Our review of the safety data and the feedback from the Safety Monitoring Committee made it clear that continued development of the highest dose was not advisable. The decision to remove the highest dose from development reduces risk to patients and it also helps to reduce risk to the overall development effort."

82. Further, in the misleading June 17, 2008 press release, Defendants stated that Defendants also learned that bapineuzumab showed no dose response, meaning that higher doses of the drug did not correlate with greater improvement of symptoms. Therefore, the only possible explanation for Defendants' exposure of carriers of the gene to a low dose of bapineuzumab in the Phase 3 Trials, when there was little basis of efficacy, a lack of evidence on dose-related benefit in all subjects, and a significant number of deaths (3) in the Phase 2 Trials in this patient group is that the lower dose was intended to generate hypotheses for further Phase 3 Trials, thus keeping the trial market share and patient enrollment in favor of bapineuzumab, as well as making the results from the non-carrier trials look better regardless of the efficacy they show. Thus, there is a serious

concern that the Phase 3 Trials in carriers are not set up, by design, to show efficacy but rather to serve as a benchmark for the Phase III trials in non-carriers, to generate further hypotheses for carriers, and to float the potential pool of subjects who, because there would no reasonable expectation that low dose therapy would be effective, otherwise may be lost to enrollment.

LOSS CAUSATION/ECONOMIC LOSS

- 83. During the Class Period, as detailed herein, Defendants engaged in a scheme to deceive investors and the market and a course of conduct that artificially inflated and maintained the price of Elan ADRs, and thus the price of the call options, and operated as a fraud or deceit on Class Period purchasers of Elan call options by misrepresenting and omitting the materially adverse results of the Phase 2 Trial. When Defendants' June 17, 2008 misrepresentations and omissions came to light and the adverse Phase 2 Trial results were finally disclosed on July 29, 2008, the price of Elan ADRs fell, as the prior artificial inflation came out of the price. As a result of their purchases of Elan's call options during the Class Period, Plaintiff and other members of the Class, suffered economic loss, *i.e.*, damages, under the federal securities laws.
- 84. As a direct result of the July 29, 2008 disclosures, the price of Elan ADRs dropped immediately. After the July 29, 2008 disclosures, the price of Elan ADRs dropped 42% in one day, falling from a July 29 close of \$33.75 per share to a July 30 close of \$19.63. Volume increased dramatically from 18 million ADRs traded on July 29 to 82 million traded on July 30 as the market reacted to the revelations about the Phase 2 Trial of bapineuzumab:



85. On July 30, 2008, the *Dow Jones* news service reported:

Elan Corp. shares plunged Wednesday as a midstage study on their experimental Alzheimer's disease drug appeared to present more questions than answers, with concerns centered around a potential safety complication and patients' response to different dosages.

The findings of the 240-patient study, which were released at the International Conference on Alzheimer's Disease on Tuesday, led Wall Street to start discounting the potential of the drug, called bapineuzumab.

т **т**

The sell-offs highlighted investor uncertainty regarding bapineuzumab's potential, following a period in which the value of both companies improved behind mounting expectations for the drug. Those expectations were fueled by partial data released June 17 that suggested benefits for a sub-group of Alzheimer's patients. However, the slide in Wyeth and Elan shares on Wednesday more than wiped out gains posted following the partial-data release.

A successful Alzheimer's drug could be a blockbuster, given the brain-harming disease affects more than 5 million Americans and the tally is likely to surge as baby boomers age. Also, there are no approved drugs today that alter the progression of the disease, kicking the door wide open for a better treatment.

- 86. Even defendant Martin conceded in the Company's October 23, 2008 earnings press release that "[t]he brief overview presentation of the Phase II data . . . at the International Conference on Alzheimer's Disease (ICAD) . . . contributed to increased volatility in our equity value and a change in the risk perception of Elan within the marketplace."
- 87. This price drop removed the inflation from the price of Elan ADRs, causing real economic loss to investors who had purchased the call options during the Class Period, which was a direct result of the nature and extent of Defendants' prior false statements and omissions being revealed to investors and the market. The timing and magnitude of these declines negate any inference that the loss suffered by Plaintiff and other Class members was caused by changed market conditions, macroeconomic or industry factors, or Company-specific facts unrelated to the Defendants' fraudulent conduct. After the July 29, 2008 disclosures, the Dow Jones Industrial Average actually increased and no analysts attributed Elan's price declines on those days to any microeconomic or industry factors. The economic loss, *i.e.*, damages, suffered by Plaintiff and other members of the Class, was a direct result of Defendants' fraudulent scheme to artificially inflate the price of Elan ADRs and maintain the price at artificially inflated levels and the subsequent significant decline in the value of Elan ADRs when Defendants' prior misrepresentations and omissions were revealed.

NO SAFE HARBOR

88. The statutory safe harbor provided for forward-looking statements does not apply to any of the allegedly false statements pleaded in this Complaint. Many of the specific statements pleaded herein were not identified as "forward-looking statements" when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the

purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker knew that the forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer and/or director of Elan who knew that the statement was false when made.

CLASS ACTION ALLEGATIONS

- 89. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased Elan's publicly traded options during the Class Period and who were damaged thereby (*i.e.*, the "Class"). Excluded from the Class are Defendants, the predecessors, successors, parents and subsidiaries of defendant Elan, Wyeth, and Pfizer, the current or former officers, directors, partners, and other employees of the Defendants, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns; and any entity in which Defendants have or had a controlling interest.
- 90. The members of the Class are so numerous that joinder of all members is impracticable. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Elan or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.
- 91. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of

federal law that is complained of herein.

- 92. Plaintiff will fairly and adequately protect the interests of the members of the Class. Plaintiff is a member of the Class and will rigorously represent the interests of Class members in the same manner as he will represent his own interests. Plaintiff knows of no conflicts or antagonisms between his individual interests and those of other Class members, and Plaintiff has retained counsel competent and experienced in class and securities litigation.
- 93. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:
- (a) whether the federal securities laws were violated by Defendants' acts as alleged herein;
- (b) whether statements made by Defendants to the investing public during the Class Period misrepresented material facts or omitted to disclose material information that, under the circumstances, would render the statements made not false and misleading;
- (c) whether Defendants acted knowingly or recklessly in making materially false and misleading statements or omitting to disclose material information that, under the circumstances, would render the statements made not false and misleading during the Class Period;
- (d) whether the prices of Elan ADRs were artificially inflated or distorted during the Class Period because of Defendants' conduct complained of herein; and
- (e) whether members of the Class have sustained damages and the proper measure of damages.
- 94. Plaintiff intends to rely, in part, upon the presumptions of reliance created by the United States Supreme Court in connection with the reliance element of his claims and the claims

of the other Class members under Sections 10(b) and 20(a) of the Exchange Act and, therefore, individual questions regarding reliance do not predominate. In particular, with respect to Defendants' material omissions alleged herein, reliance by Plaintiff and the other members of the Class is presumed. With respect to Defendants' affirmative misrepresentations alleged herein, reliance by Plaintiff and the other members of the Class is presumed under the fraud-on-themarket doctrine, because, at all relevant times, the market for Elan ADRs was efficient for the following reasons, among others:

- (a) Elan ADRs traded in an efficient market, the NYSE, under the symbol ELN. Elan ADRs also traded on the LSE.
 - (b) As a regulated issuer, Elan filed periodic public reports with the SEC;
- (c) Elan regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and
- (d) Elan was followed by numerous securities analysts and investment market professionals.
- 95. As a result of the foregoing, the market for Elan ADRs rapidly absorbed all publicly material information regarding Elan and that information was reflected in the price of Elan ADRs.
- 96. Plaintiff and other members of the Class purchased Elan's publicly traded call options between the time that Defendants made the material misrepresentations and omissions alleged herein and when the truth was finally and fully revealed to the public.
- 97. Plaintiff is thus entitled to a presumption that all purchasers of Elan's publicly traded call options during the Class Period suffered similar injury because they paid inflated prices

in reliance on Defendants' material misrepresentations and/or omissions and/or in reliance on the integrity of the prices for Elan ADRs, and suffered economic losses when the price of Elan ADRs declined in value in direct, proximate and consequential response July 29, 2008 disclosure.

98. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

COUNT I

Violation of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder (Against Defendants)

- 99. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.
- 100. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; and (ii) cause Plaintiff and other members of the Class to purchase publicly traded call options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.
- 101. Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's publicly traded call options

in an effort to maintain artificially high market prices for Elan ADRs in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All of the Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

- 102. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about Elan.
- 103. These Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Elan's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and/or omitting to state material facts necessary in order to make the statements made about Elan in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of Elan's publicly traded call options during the Class Period.
- 104. Each of the Individual Defendants' primary liability, and controlling person liability, arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of these Individual Defendants enjoyed significant personal contact and familiarity with the other Defendants and was advised of, and had access to, other members of the Company's management team, internal reports and other data and information about the Company at all relevant times; and (iii) each of these Individual Defendants was aware of the Company's dissemination of information to the investing public which they knew or recklessly disregarded was materially false and misleading.

- 105. Defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such the Defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing the truth from the investing public and supporting the artificially inflated price of Elan ADRs. Defendants, if they did not have actual knowledge of the misrepresentations and omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.
- and failure to disclose material facts, as set forth above, the price of Elan ADRs was artificially inflated during the Class Period. In ignorance of the fact that price of Elan ADRs was artificially inflated, and relying directly or indirectly on the false and misleading statements made by the Defendants, or upon the integrity of the market in which Elan ADRs traded, and/or in the absence of material adverse information that was known to or recklessly disregarded by Defendants, but not disclosed in public statements by Defendants during the Class Period, Plaintiff and the other members of the Class purchased Elan's publicly traded call options during the Class Period at artificially high prices and were damaged thereby.
- 107. At the time of said misrepresentations and omissions, Plaintiff and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff and the other members of the Class and the marketplace known the truth, which was not disclosed by Defendants, Plaintiff and other members of the Class would not have purchased their publicly traded call options, or, if they had acquired them during the Class Period, they would not have done so at the artificially inflated prices which they paid.

- 108. By virtue of the foregoing, Defendants have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.
- 109. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's publicly traded call and put options during the Class Period.

COUNT II Violation of Section 20(a) of the Exchange Act (Against the Individual Defendants)

- 110. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.
- 111. The Individual Defendants acted as controlling persons of Elan within the meaning of Section 20(a) of the Exchange Act and are liable thereunder. As senior officers and/or directors of Elan, high-level executives of the Company, "hands on" supervisors, decision-makers and participants in Elan's operations, the Individual Defendants had the power and authority to influence and control and did influence and control Elan to engage in the wrongful conduct complained of herein.
- 112. In particular, each of these Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.
- 113. As set forth above, Elan and the Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of the Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their purchases of the

Company's publicly traded call options during the Class Period.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

A. Determining that this action is a proper class action under Rule 23 of the Federal

Rules of Civil Procedure;

B. Awarding compensatory damages in favor of Plaintiff and the other Class members

against Defendants, jointly and severally, for all damages sustained as a result of Defendants'

wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Plaintiff and the Class their reasonable costs and expenses incurred in

this action, including attorneys' fees and expert fees; and

D. Such other and further relief as the Court may deem just and proper.

JURY DEMAND

Plaintiff demands a trial by jury.

Dated: July 23, 2010

Respectfully submitted,

BROWER PIVEN

A Professional Corporation

David A.P. Brower

488 Madison Avenue, Eighth Floor

New York, New York 10022

Telephone: (212) 501-9000

Facsimile: (212) 501-0300

ALMERICO & MOONEY

Brian G. Mooney

4350 W. Cypress Street, Suite 820

Tampa, Florida 33607

Telephone: (813) 877-1800

Counsel for Gary W. Kleinman

EXHIBIT A

PLAINTIFF'S CERTIFICATION

Gary Kleinman ("Plaintiff") declares that:

I. I have reviewed the complaint to which this Certification is attached and adopt, and

authorize the filing of, such complaint.

Plaintiff did not purchase the security that is the subject of this action at the direction of

plaintiff's counsel or in order to participate in this private action.

3. Plaintiff is willing to serve as a representative party on behalf of the class, including

providing testimony at deposition and trial, if necessary, and Plaintiff is willing to serve as a lead

plaintiff either individually or as part of a group, a lead plaintiff being a representative party who acts on

behalf of other class members in directing the action.

4. Plaintiff's transactions in Elan Corporation, plc securities during the Class Period are

attached hereto.

5. During the three years prior to the date of this Certification, Plaintiff has not sought to

serve or served as a representative party for a class under the federal securities laws other than the case of

In re Elan Corporation Securities Litigation, No. 1:08-cv-08761-AKH (S.D.N.Y.).

6. Plaintiff will not accept any payment for serving as a representative party on behalf of

the class beyond the Plaintiff's pro rata share of any recovery, except such reasonable costs and expenses

(including lost wages) directly relating to the representation of the class as ordered or approved by the

court. Plaintiff understands that this is not a claim form, and that Plaintiff's ability to share in any

recovery as a member of the class is unaffected by Plaintiff's decision to serve as a representative party.

I declare under penalty of perjury under the laws of the United States of America that the

foregoing is true and correct. Executed this \(\sqrt{O} \) day of July 2010.

Gary Kleinman

Brower Piven, A Professional Corporation

1925 Old Valley Road

Stevenson, Maryland 21153 Telephone: 410-332-0030

Facsimile: 410-685-1300

www.browerpiven.com

Gary W. Kleinman

Elan Corporation, plc

Schedule of Transactions

Date	Option	Type	Contracts	Price Per Contract
6/18/2008	July Call \$17.50	SELL	2,000	\$1,200.00
6/25/2008	July Call \$25.00	BUY	1,129	\$850.00
7/3/2008	July Call \$25.00	BUY	1,371	\$953.59
7/3/2008	July Call \$25.00	BUY	500	\$950.00
7/11/2008	July Call \$25.00	BUY	146	\$960.00
7/14/2008	July Call \$25.00	BUY	854	\$926.14
7/17/2008	July Call \$25.00	SELL	2,000	\$706.89
7/17/2008	July Call \$25.00	SELL	2,000	\$791.89
7/17/2008	Oct. Call \$20.00	BUY	2,000	\$1,425.01
7/17/2008	Oct. Call \$20.00	BUY	2,000	\$1,391.89
7/25/2008	Oct. Call \$20.00	SELL	50	\$1,420.00